REMARKS/ARGUMENTS

The Examiner is thanked for explaining very clearly the remaining issues to be resolved. Applicant has amended the claims in a manner believed to overcome the objections raised by the Examiner.

Specifically, in response to the Examiner's rejections under 35 U.S.C. §112, second paragraph, claims 12, 13, 34 and 35 have been amended. The "B-ring" has been more specifically identified as the "ring carbon to which R_{100} is attached". The term "derivative", to which the Examiner had objected, has been canceled. It is pointed out that the bivalent moiety R_{100} is for the purpose of properly spacing the other members of the molecular structure. Given this function, there is an expectation that a significant breadth of chemical moieties would be appropriate at this location. Accordingly, it is believed that the claims particularly point and distinctly claim the subject matter that applicant regards as the invention. In view of the amendments, it is urged that the Examiner's rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

The claims stand rejected under 35 U.S.C. §112, first paragraph, as allegedly overbroad in the recitation of selective estrogen receptor modulators and in the recitation of estrogens. It is noted, however, that the invention seeks to affect estrogen receptor response in various tissues. It is well known that a variety of estrogens affect this response in a similar manner. It is permissible for a patent claim to recite a class of materials when, as here, there is reason to expect each member of the class to perform similarly in the context of the invention. In the present claims, there are recitations of a classes of like-functioning materials (e.g., estrogens) Such recitations of a class of materials is proper under 35 U.S.C. §112, first paragraph, wherever the specification would lead one of skill in the art to expect and predict that specific members of the class will interchangeably provide the same function in the invention. In Re Hirschler, 591 F.2d 693, 701, 200 U.S.P.Q. 711 (C.C.P.A. 1979). Even if the materials may perform different functions, in other contexts, they may nevertheless be claimed as a class where they perform the same function in the invention. id. For example, the application at issue in Hirschler gave only a single example of a single steroid (dexamethasone 21-phosphate), in a claim that broadly recited all "steroids" as a class of materials whose penetration of human skin could be enhanced with DMSO. The Court of Customs and Patent

Appeals permitted broad claim language to "steroids" generically. The Court pointed out that although different steroids have vastly different functions biologically (consider, for example, male steroids such as testosterone versus female steroids such as estradiol), the entire class of steroids would act identically in the context of the claimed invention (i.e. in enjoying DMSO-enhanced skin penetration). The Court noted:

> The question is simple: does the array of information supplied by appellant in the [relevant] application teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process. We conclude that it does.
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> Steroids, when considered as drugs, have a broad scope of physiological activity. On the other hand, steroids when considered as a class of compounds carried through a layer of skin by DMSO, appear on this record to be chemically quite similar.

Hirschler, 591 F.2d at 701, 200 U.S.P.Q. at 717 (emphasis added).

Where the members of the generically recited class are expected to perform similarly in the invention, the dictates of §112 are met. There is no magic number of specific examples required. A single example was sufficient in Hirschler. Indeed, a specification without any examples can be sufficient in the appropriate case. See, e.g., In re Strahilevitz, 668 F.2d 1229, 1232, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982); In re Stephens, 529 F.2d 1343, 1345, 188 U.S.P.Q. 659, 661 (C.C.P.A. 1976); In re Borkowski, 422 F.2d 904, 908, 164 U.S.P.Q. 642, 645 (C.C.P.A. 1970); In re Gay, 309 F.2d 769, 774, 135 U.S.P.Q. 311, 316 (C.C.P.A. 1962). All that is required is a rational basis for expecting that the advantages of the invention will not be lost simply because one member of a generically recited class is chosen instead of another. For all of the foregoing reasons, it is urged that the Examiner's rejection under 35 U.S.C. §112 should be withdrawn.

The claims stand rejected under 35 U.S.C. §103 as allegedly obvious over Luo et al., Barrett-Connor et al., and Do Nascimento in view of Labrie '201.

It is believed that the obviousness rejection is based, in part, on a misunderstanding of the teachings of Luo. DHEA is not an estrogen, but rather a sex steroid precursor that is primarily androgenic. Those of skill in the art would not classify DHEA as an estrogen. The claims would

not cover the mere combination of DHEA and EM-800 as shown in Luo. The remaining references cited by the Examiner do not overcome this deficiency in Luo because the remaining references do not relate to the claimed combination therapy at all. Applicant has surprisingly found that SERMs and estrogens can provide significant benefits when used in combination. This was not predictable from the prior art. Indeed, one of the primary functions of SERMs, in many tissues, is to act as an estrogen receptor antagonist. Using estrogen (an agonist) in combination with SERM (which acts as an antagonist in many tissues) would not be suggested by the Examiner's cited art.

Accordingly, it is urged that the rejection under 35 U.S.C. 103 should be withdrawn.

It is believed that the application is now in condition for allowance. Issuance of a Notice of Allowance is solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 13, 2004:

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Respectfully submitted,

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